BerGenBio Announces First Patient Dosed in Phase 1b/2a Trial Evaluating Bemcentinib in 1st Line Non-Small Cell Lung Cancer with STK11 Mutations

- Global trial designed to study the safety, tolerability and efficacy of bemcentinib in combination with current standard of care –

BERGEN, Norway, March 9, 2023 – BerGenBio ASA (OSE: BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for severe unmet medical needs, today announced the first patient was dosed in a Phase 1b/2a trial evaluating *bemcentinib* in combination with the current standard of care, immune checkpoint inhibitor pembrolizumab and doublet chemotherapy, for the treatment of 1st line (1L) Non-Small Cell Lung Cancer (NSCLC) patients harboring STK11 mutations (STK11m).

“Approximately 20% of non-squamous NSCLC patients harbor STK11m and do not currently have effective treatment options,” said Martin Olin, Chief Executive Officer of BerGenBio. “One specific attribute of this group is that they almost all demonstrate high levels of AXL activation. We are elated to have dosed the first patient in our trial and to continue our evaluation of *bemcentinib* and its ability to inhibit AXL to revive STK11m NSCLC patients’ response to checkpoint inhibitors and chemotherapy.”

The trial’s lead investigator, Rajwanth Veluswamy, M.D., MSCR, Assistant Professor of Medicine, Hematology and Medical Oncology, Icahn School of Medicine at Mount Sinai (New York, NY), commented, “Today, STK11 mutations are correlated with a very poor prognosis for patients suffering from NSCLC. These mutations are widely recognized for their ability to impede the activity of anti-PD-1/L1 therapy. My colleagues and I are driven to find a better outcome for this large patient population and are eager to assess *bemcentinib*’s potential in achieving this goal.”

The global, open-label Phase 1b/2a trial is designed to determine the safety, tolerability and efficacy of *bemcentinib* with standard of care treatments in untreated advanced/metastatic non-squamous NSCLC patients with STK11 mutations and no actionable mutations. The Phase 1b portion of the study will evaluate the safety and feasibility of *bemcentinib* in combination with pembrolizumab and doublet chemotherapy in 1L advanced/metastatic non-squamous NSCLC patients, regardless of STK11 status. The Phase 2a expansion part will assess the efficacy of bemcentinib in the same treatment combination in 1L advanced/metastatic non-squamous NSCLC patients with STK11 mutations.

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About BerGenBio ASA

BerGenBio is a clinical-stage biopharmaceutical company focused on developing transformative drugs targeting AXL as a potential cornerstone of therapy for aggressive diseases. The Company is focused on advancing its lead candidate, bemcentinib, a potentially first-in-class, oral, selective AXL inhibitor in STK11 mutated NSCLC and severe respiratory infections including COVID-19.

BerGenBio is based in Bergen, Norway with a subsidiary in Oxford, UK. The company is listed on the Oslo Stock Exchange (ticker: BGBIO). For more information, visit www.bergenbio.com

Forward looking statements

This announcement may contain forward-looking statements, which as such are not historical facts, but are based upon various assumptions, many of which are based, in turn, upon further assumptions. These assumptions are inherently subject to significant known and unknown risks, uncertainties, and other important factors. Such risks, uncertainties, contingencies and other important factors could cause actual events to differ materially from the expectations expressed or implied in this announcement by such forward-looking statements.

This information is subject to the disclosure requirements pursuant to section 5-12 of the Norwegian Securities Trading Act.